IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
Group Art Unit 1652

In re

Patent Application of

Leslie A. Holladay

Application No. 10/016,403

Confirmation No. 4840

Filed: December 10, 2001

Examiner: Steadman, David J.

"MODIFICATION OF POLYPEPTIDE DRUGS
TO INCREASE ELECTROTRANSPORT FLUX"

I, Sally Sorensen, hereby certify that this correspondence is being deposited with the US Postal Service as first class mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date of my signature.

Sally Sorensen
Signature

March 24, 2004
Date of Signature

RESPONSE TO RESTRICTION REQUIREMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This is in response to the restriction requirement mailed December 24, 2003. Transmitted herewith, please find a petition and fee for a two month extension of time, extending the due date for response to the Office Action from January 24, 2004 to March 24, 2004. Applicant submits, therefore, that this response is timely filed.

The Examiner has required restriction to one of three groups. The claims in Group I (1-2, 4 and 17-21) are drawn to a method for delivering a pharmaceutical polypeptide agent by providing a synthetic analog of human granulocyte colony stimulating factor. The claims in Group II (1-2, 4 and 22-24) are drawn to a method for delivering a pharmaceutical polypeptide agent by providing a synthetic analog of human parathyroid hormone. The claims of Group III (1-2, 4 and 25-27) are drawn to a method for delivering a pharmaceutical

polypeptide agent by providing a synthetic analog of human growth releasing hormone. Applicant elects with traverse the claims of Group III.

Restriction Improper

There must be a serious burden on the Examiner in order for restriction to be required. The Manual of Patent Examining Procedure ("MPEP") states that:

> "If the search and the examination of an entire application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to distinct or independent inventions." MPEP § 803

Restriction is improper, as there is no such burden on the Examiner in this case. Applicant respectfully submits that the Examiner has already agreed to provide a search and examination of a scope broad enough to encompass all of the claims of the application. When Applicant elected Group I, claims 1, 2, 4, 17-28, after the first restriction requirement, the Examiner agreed to search and examine the broad independent claim 1. Presumably the Examiner has already performed such a search and examination in preparation of the Office Action mailed March 6, 2003. Any arguable burden provided by the new, more limitative claims, would be a search and examination of the same scope as inherently agreed to by the Examiner with the search and examination of claim 1.

The Examiner originally issued a first restriction requirement in this application on September 24, 2002. The Examiner set forth Group I as being claims 1, 2, 4 and 17-18 which are drawn to a method for delivering a pharmaceutical polypeptide agent through a body surface. Applicant elected this group and subsequently the Examiner issued an Office Action on March 6, 2003. The Office Action contained a substantive examination of the claims, including rejecting certain claims as being obvious over various prior art references. Applicant responded to this rejection on September 8, 2003. In this response Applicant added new claims 19-27 which further depend from claim 1, and contain additional limitations. As the new claims 19-27 contain further limitations than claim 1, the search and

examination that was preformed on claim 1 in preparing the Office Action of March 6, 2003 should already encompass what needs to be searched for the new claims. Presumably if applicant had not added these new claims, the Examiner would continue examination of the application which would include further searches and examination of claim 1. The scope of such search and examination would inherently cover any art which would be applicable to new claims 19-27. Applicant respectfully submits that there cannot be any additional burden to examine all of the claims of the application together, as the examination of elected claim 1 is of a scope which inherently encompasses the other dependant claims of the application.

The search is also not burdensome as the claims of the various groups designated by the Examiner are in the same class and subclass. As the Examiner will already be extensively searching this class and subclass when examining any of the groups, there would be no additional burden to examine all of the claims of the application together.

Claim Grouping Improper

The Examiner has indicated that the claim groupings are due to the different polypeptide agents claimed in claims 19-21 of Group I, claims 22-24 of Group II, and claims 25-27 of Group III. Claims 17 and 18 are claims which are dependant on claim 1, but are not drawn to any of the specific polypeptides in claims 19-21, 22-24 and 25-27. As such, given the Examiners reasoning, these claims should be part of each claim group argued by the Examiner.

Claim 1 is Generic

Claims 2, 4 and 17-27 depend directly or indirectly on claim 1. The scope of claim 1 inherently covers all of the specific polypeptides listed in claims 19-21 of Group I, claims 22-24 of Group II, and claims 25-27 of Group III. Claim 1, therefore, should be considered a generic claim linking the specific polypeptides of claims 19-21, 22-24 and 25-27. If the Examiner does not withdraw the restriction requirement as requested above, the Examiner